



## PATENT APPLICATION

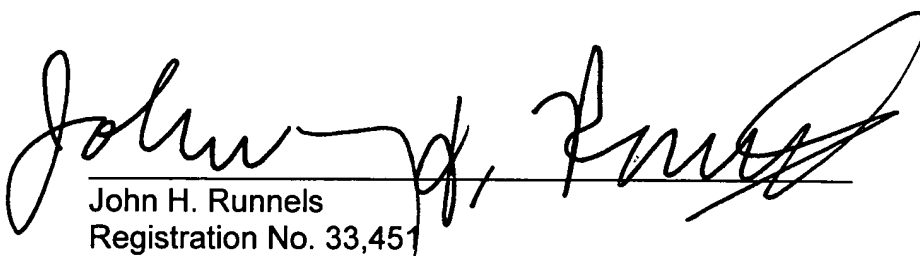
### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Eugene A. Woltering *et al.*                      Group: 1651  
Serial No.: 09/866,296    Examiner: Afremova, Vera  
Filing Date: May 25, 2001  
Title: Three-dimensional Ex Vivo Angiogenesis System  
File No.: Woltering 98M06.1

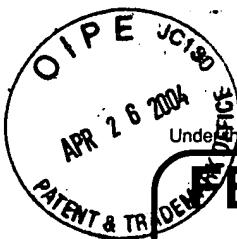
### CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that the listed enclosures are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 21, 2004.

- Reply Under 37 C.F.R. § 1.111
- Declaration of Eugene A. Woltering
- Fee Transmittal Sheet
- Check for \$110.00
- Return postcard verifying receipt of the listed enclosures

  
John H. Runnels  
Registration No. 33,451

April 21, 2004



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PTO/SB/17 (10-03)  
Approved for use through 07/31/2006. OMB 0651-0032  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

<b>FREE TRANSMITTAL for FY 2004</b> <i>Effective 10/01/2003. Patent fees are subject to annual revision.</i>		<b>Complete if Known</b>	
		Application Number	09/866,296
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Filing Date	May 25, 2001
		First Named Inventor	Eugene A. Woltering
TOTAL AMOUNT OF PAYMENT (\$)		Examiner Name	Afremova, Vera
		Art Unit	1651
		Attorney Docket No.	98M06.1 Woltering

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<b>SUBMITTED BY</b>		<b>Complete (if applicable)</b>	
Name (Print/Type)	John H. Runnels	Registration No. (Attorney/Agent)	35,491
Signature		Telephone	(225) 387-3221
		Date	April 21, 2004

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

*Eugene*

1651\$



**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of

Group 1651

Eugene A. Woltering *et al.*

Examiner Afremova, Vera

Serial No. 09/866,296

Filing Date May 25, 2001

For: Three-Dimensional *Ex Vivo* Angiogenesis System (File No. 98M06.1 Woltering)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY UNDER 37 C.F.R. § 1.111**

Dear Sir:

This Reply is submitted in response to the Official Action dated January 13, 2004.

No further amendments are presented. Claims 1-10, 13, 38, and 39 remain pending in the application.

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**CERTIFICATE**

I hereby certify that this Reply under 37 C.F.R. § 1.111 and the accompanying check for \$110.00 are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 21, 2004.

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01 FC:1251

110.00 OP

*John H. Runnels*  
\_\_\_\_\_  
John H. Runnels  
Registration No. 33,451  
April 21, 2004

Enclosed is a check for \$110 for a one-month extension of time, to extend the time for response from April 13, 2004 to May 13, 2004. (37 C.F.R. § 1.136(a)(3)). If this amount is incorrect, please refer to the Deposit Account Authorization previously filed for this application. If any additional extension of time is required, please consider this paper a petition for the total extension of time required.

The January 13, 2004 Office Action had the effect of withdrawing all prior grounds of rejection and objection, and of entering two new grounds of rejection.

Reexamination and reconsideration of the application are respectfully requested.

### **The § 112, First Paragraph Rejection**

Claims 1-5, 7, 8, 10, 13, 38, and 39 were rejected on the ground that the specification "does not reasonably provide enablement for enabling for method of assaying angiogenic potential of a three-dimensional tumor embedded in collagen-containing matrix." (January 13, 2004 Office Action, p. 3).

As paragraphs 2-6 of the enclosed Declaration of inventor Dr. Eugene Woltering demonstrate, the method has been successfully demonstrated in a collagen-containing matrix, namely, one based on ECM gel. The experiments described in Dr. Woltering's Declaration were conducted in essentially the same manner as those reported in the original specification, except as noted, particularly the substitution of a collagen-containing system for the fibrin/thrombin clot system. Obtaining successful results with the collagen-based system was straightforward; undue experimentation was not required.

As Dr. Woltering's Declaration notes (Paragraphs 5, 6), the collagen-based system was less efficient than the fibrin/thrombin clot system. But more important is the fact that the collagen-based system did work, as the specification had correctly predicted.

It is respectfully submitted that the enablement ground of rejection should be withdrawn.

### **The §§ 102 and 103 Rejections**

Claims 1-6, 9, 13, 38, and 39 were rejected under 35 U.S.C. §§ 102(a) and 103 as being anticipated by, or obvious over, the Gulec *et al.* paper, either taken alone or in combination with a secondary reference.

As paragraphs 7-10 of the enclosed Declaration of inventor Dr. Eugene Woltering demonstrate, the Gulec *et al.* paper represents a publication of the inventors' own work. Because the paper was published in May 2001, less than one year before the nearly-contemporaneous May 2001 filing date of the present application, the Gulec *et al.* paper has been removed as a reference.

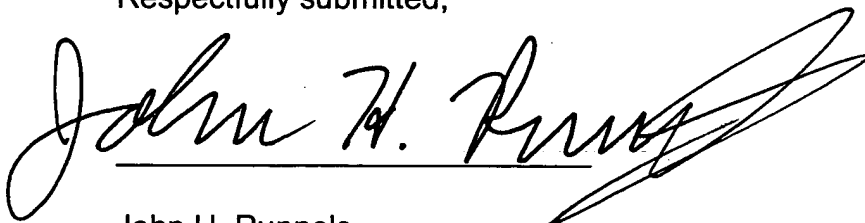
Applicants also note that the Gulec *et al.* paper was published after the May 2000 provisional filing date whose priority has been claimed under 35 U.S.C. § 119(e). While the provisional priority claim provides an additional basis to remove the Gulec *et al.* paper as a reference, it is not necessary to examine the disclosure of the priority application in detail to resolve this question. Even if one disregarded the effect of the priority application, the paper would still represent a publication of the Applicants' own work made less than one year prior to the filing date of the present application.

It is respectfully submitted that the Gulec *et al.* paper has been removed as a reference, that all prior art rejections have thereby been overcome, and that all §§ 102 and 103 rejections should therefore be withdrawn.

## Conclusion

Allowance of Claims 1-10,13, 38, and 39 at an early date is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "John H. Runnels". The signature is written in a cursive style with a large, sweeping initial "J" and a long, horizontal flourish extending to the right.

John H. Runnels  
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April 21, 2004